UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

No.: 1:15-CV-07488-CM-RWL

[~~PROPOSED~~] REVISED JOINT PRETRIAL ORDER

The parties having conferred among themselves and with the Court pursuant to Federal Rule of Civil Procedure 16, the following statements, directions and agreements are adopted as the Pretrial Order herein. The parties note that any Court decision on forthcoming Motions *in Limine* and other motions may alter the scope of the case and thus, may warrant revising portions of this pretrial order, including the issues to be tried, the parties' exhibits, the parties' witness lists, the parties' deposition designations, the parties' contentions, and the parties' jury instructions.

I. NATURE OF THE CASE

This is an antitrust action arising under Sections One and Two of the Sherman Antitrust Act challenging two forms of allegedly anticompetitive conduct relating to two of Forest's Namenda products — Namenda IR and Namenda XR.

Plaintiffs challenge (1) the legality and effect of the payment and entry date terms of Forest's agreement to settle litigation with Mylan over the Namenda IR patent ("reverse payment allegations"), and (2) the effect of Forest's conduct associated with its announced withdrawal of branded Namenda IR ("hard switch allegations"). Plaintiffs seek damages for these claims.

With respect to Plaintiffs' hard switch allegations, Forest disagrees with Plaintiffs' ability to challenge Forest's "conduct associated with" its announced withdrawal in light of the Court's collateral estoppel order defining the hard switch. Regardless, Forest denies that its conduct with respect to the reverse payment allegations or the hard switch allegations was in violation of the law or otherwise injured Plaintiffs.

II. JURY/NON-JURY

The parties agree that the case shall be tried by a jury. The parties estimate that the trial will take approximately six (6) weeks. The parties request that trial be conducted using a chess clock and that each side be allocated 60 hours each, not including opening and closing arguments.

III. STIPULATED FACTS

The parties stipulate as follows:

A. The Parties

1. Plaintiff J.M. Smith Corporation d/b/a Smith Drug Company ("Smith Drug Company") is a corporation organized under the laws of the State of South Carolina and is located at 9098 Fairforest Road, Spartanburg, South Carolina 29301.

2. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC"), is a corporation organized under the laws of the State of New York and is located at 50 Jet View Drive, Rochester, New York 14624.

3. Defendant Forest Laboratories, LLC (successor-in-interest to Defendant Forest Laboratories, Inc.) ("Forest") is a limited liability company organized under the laws of the State of Delaware and has a principal place of business at 5 Giralda Farms, Madison, NJ 07940. Forest is now a wholly-owned subsidiary of Allergan, plc.

4. Defendant Forest Laboratories Holdings Ltd. is incorporated under the laws of Ireland.

5. Defendant Actavis plc, now known as Allergan plc, is incorporated under the laws of Ireland.

B. Venue

6. Venue is proper in the United States District Court for the Southern District of New York.

C. Marketing of Namenda

7. Memantine hydrochloride is prescribed to treat moderate to severe Alzheimer's disease.

8. In December 2002, Forest submitted New Drug Application ("NDA") No. 21-487 to the United States Food and Drug Administration ("FDA"), seeking approval to market memantine hydrochloride tablets (5mg and 10mg) – branded as Namenda – for the treatment of Alzheimer's.

9. On October 16, 2003, the FDA approved Forest's NDA for twice-daily Namenda immediate release ("IR") tablets for use in patients with moderate to severe Alzheimer's disease.

10. In January 2004, Forest commercially launched Namenda IR tablets in the United States.

11. On June 16, 2014, the FDA granted pediatric exclusivity to Forest.

12. Forest submitted NDA No. 22-525 for Namenda XR on August 20, 2009, seeking approval to market once-daily extended release memantine hydrochloride tablets (7mg, 14mg, 21mg, and 28mg) – branded as Namenda XR – for the treatment of Alzheimer's.

13. Forest launched Namenda XR on June 13, 2013.

D. The '703 Patent

14. Merz Pharma GmbH & Co. KGaA ("Merz"), a German company, owns U.S. Patent No. 5,061,703 ("the '703 patent") which claims methods of treatment using memantine.

15. In June 2000, Forest obtained an exclusive license to market a memantine hydrochloride product in the United States under Merz's '703 patent.

16. The '703 patent, issued on October 29, 1991, is entitled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia."

17. The '703 patent was originally set to expire on April 11, 2010.

18. On March 3, 2009, the United States Patent and Trademark Office extended the expiration date of the '703 patent to April 11, 2015.

E. Forest/Mylan Lexapro Agreements

19. Escitalopram oxalate ("escitalopram") is the active pharmaceutical ingredient in the branded drug Lexapro.

20. Lexapro was developed by Forest and H. Lundbeck A/S ("Lundbeck"), a Danish pharmaceutical firm which licensed the exclusive United States marketing rights to escitalopram to Forest.

21. On May 29, 2002, Lundbeck and Forest entered the S-enantiomer License Agreement, whereby Lundbeck granted Forest a license to market Lexapro.

22. Forest submitted NDA 02-1323 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexapro, and the FDA approved Forest's NDA on August 14, 2002.

23. In September of 2002, Forest launched Lexapro.

24. On October 3, 2005, Forest and Alphapharm Pty, Ltd. ("Alphapharm") entered into a Distribution and Supply Agreement for authorized generic Lexapro (the "Original Lexapro Agreement").

25. Mylan acquired Alphapharm in 2007.

26. On July 21, 2010, Alphapharm, the original counterparty to the Original Lexapro Agreement, appointed Mylan as its assignee, and Forest and Mylan executed an amendment to the Original Lexapro Agreement (the "Lexapro Amendment").

IV. PARTIES' CONTENTIONS

Plaintiffs' contentions are appended hereto as Exhibit 1.

Defendants' contentions are appended hereto as Exhibit 2.

V. ISSUES TO BE TRIED

After substantial efforts to reach agreement regarding the issues to be tried, the parties have agreed to each submit their own proposed statements of issues to be tried.

A. Plaintiffs' [PROPOSED] Statement of the Issues to Be Tried:

1. Did Defendants enter into a reverse payment agreement with Mylan that unreasonably restrained trade?

2. Without the reverse payment to Mylan, would one or more companies have launched a version of generic Namenda IR before July 2015? And if so, which generics would have so launched, and when would such launches have occurred?

3. Without Defendants' hard switch product hop and/or reverse payment to Mylan, would the Direct Purchaser Class have made some purchases of a form of memantine hydrochloride at prices lower than the prices they actually paid?

4. What are the total overcharge damages of the Direct Purchaser Class?

B. Defendants' [PROPOSED] Statement of the Issues to Be Tried:

Reverse Payment Allegations

1. Did Defendants make a large and unexplained reverse payment to Mylan, in excess of fair value for services obtained from Mylan, Defendants' saved litigation costs, or other traditional settlement considerations, for the purpose of delaying generic Namenda IR entry, and did that payment in fact delay generic Namenda IR entry?

2. If so, absent the large and unexplained reverse payment, would Mylan have sold generic Namenda IR earlier than July 11, 2015 by either (1) entering into an alternative settlement agreement with Forest, allowing Mylan to sell generic Namenda IR on November 2, 2012; or (2) continuing the patent litigation and prevailing, thereby obtaining the right to launch by June 2012?

3. If so, what amount of damages have Plaintiffs and the proposed class proven, if any, were caused by Defendants' large and unexplained reverse payment?

Hard Switch Allegations

4. Did Defendants' February 14, 2014 announcement of its planned discontinuation of Namenda IR cause patients to switch to Namenda XR prior to the December 2014 injunction?

5. If so, how many individuals (if any) that switched to Namenda XR as the result of the February 14, 2014 announcement stayed on Namenda XR beyond July 2015 (despite the December 2014 injunction and Forest's continued-availability announcements) because they were coerced by the withdrawal announcement, and not because of the benefits of Namenda XR?

6. What amount of damages have Plaintiffs and the proposed class proven, if any, were caused by Namenda XR purchases after July 2015 by those individuals identified in the prior paragraph?

VI. PLAINTIFFS' EXHIBITS

Plaintiffs' exhibit list (including Defendants' objections) is appended hereto as Exhibit 3. Plaintiffs' exhibits are numbered PX-0001 through PX-1709. However we have narrowed the total number of proposed Plaintiffs' exhibits since the original January, 2018 Proposed Pre-Trial Order such that the total number of proposed Plaintiffs' exhibits currently stands at 998. The exhibits that have been removed from our exhibit list are demarcated as "Intentionally Left Blank." As part of the hard copy exhibits provided to the Court, Plaintiffs have included a USB drive. The hard copy slip sheets for the native files are denoted as either "No tiff included for this record"; "Document Produced Natively"; or "Produced As Native."

Plaintiffs have followed the exhibit naming convention expressly mandated by this Court in its Individual Rules of Practice. Specifically, Plaintiffs have stamped their trial exhibits with the "PX-" prefix. Plaintiffs' stamp is unlikely to be confused with any other markings, including markings from the 2014 New York Attorney General litigation concerning Forest's Namenda hard switch, because Plaintiffs' stamp in this litigation has a unique border, font and a recites the caption text. Plaintiffs disagree with Forest that Plaintiffs' exhibits need to be reprinted.

VII. DEFENDANTS' EXHIBITS AND OBJECTIONS TO PLAINTIFFS' EXHIBITS

A. Defendants' Exhibits

Defendants' exhibit list (including Plaintiffs' objections) is appended hereto as Exhibit 4.

Defendants' exhibits are numbered DTX-001 through DTX-776. However, Defendants have removed several exhibits since the original January 2018 Proposed Pre-Trial Order, while keeping the exhibit numbering consistent. As such, the total number of proposed Defendants' exhibits currently stands at 628.

As part of the hard copy set of exhibits delivered to the Court, Defendants have also included a disk that contains native electronic Excel files for those documents that could not be converted to a usable PDF exhibit. Defendants have indicated in the last column of the exhibit list which exhibits include native Excel files.

Defendants are aware that the Court's Individual Rules of Practice specify that the parties should use the prefix "PX" and "DX" for exhibit stamping. Prior to the January 2018 Pretrial Order filing, the parties agreed to use the exhibit prefixes "PTX" and "DTX" because certain documents produced in this action already had trial exhibit stamps with "PX" and "DX" from the 2014 NYAG action, and the parties wanted to avoid confusion. The parties continued using those "PTX" and "DTX" prefixes in exchanges in preparing for this revised submission up until April 26, 2019 when DPPs unilaterally, and without notice, changed their exhibit prefix to "PX." At that point, hard copies of the exhibits had already been stamped and printed for the Court. Thus, Defendants' exhibits are stamped with the prefix "DTX," while Plaintiffs' exhibits are stamped with the prefix "PX." Defendants believe that to ensure consistency and avoid confusion, Plaintiffs should re-stamp their exhibits using the prefix "PTX."

B. Defendants' Objections to Plaintiffs' Exhibits

For those proposed Plaintiffs' exhibits to which Defendants have not asserted an objection, Defendants' position is that Plaintiffs should still be required to establish the prerequisites to the exhibits' admissibility, including laying a foundation with a witness with knowledge, before the

exhibit may be admitted into evidence. Further, Defendants have not submitted specific objections to certain categories of documents because it is unclear how Plaintiffs intend to use the documents at trial. For example, Plaintiffs have listed several Forest SEC filings and investor earnings call transcripts. *See, e.g.*, PX-1595 – 1626. While Defendants do not generally object to these documents, Defendants reserve the right to object depending on how Plaintiffs intend to use the documents at trial.

VIII. STIPULATIONS AND OBJECTIONS WITH RESPECT TO EXHIBITS

The parties stipulate that the following exhibits are deemed authentic:

Ex.	Bates Range
PX-0035/DTX-072	FRX-AT-00000001 - 037
PX-1130/DTX-073	FRX-AT-00000038 - 075
PX-1131/DTX-074	FRX-AT-00000076 - 111
PX-0525/DTX-075	FRX-AT-00000112 - 147
PX-1132/DTX-076	FRX-AT-00000148 - 183
PX-0321/DTX-077	FRX-AT-00000184 - 217
PX-0002/DTX-078	FRX-AT-00000218 - 252
PX-0024/DTX-012	FRX-AT-00000253 - 273
PX-1133/DTX-079	FRX-AT-00000274 - 308
PX-1134/DTX-080	FRX-AT-00000309 - 339
PX-1135/DTX-081	FRX-AT-00000340 - 379
PX-0196/DTX-082	FRX-AT-00000380 - 416
DTX-083	FRX-AT-00000417 - 427
PX-0019/DTX-084	FRX-AT-00000428 - 463
PX-0030/DTX-013	FRX-AT-00000464 - 477
DTX-085	FRX-AT-00000478 - 514

The parties' objections to exhibits are detailed in Exhibits 3 and 4.

IX. WITNESS LISTS

The parties' deposition designations and objections are appended hereto as Exhibit 5.

The parties will provide the Court with deposition transcripts upon request by the Court and will narrow the number of objections presented to the Court for rulings.

A. PLAINTIFFS' WITNESS LIST

Listed below are all the witnesses Plaintiffs intend to call. Plaintiffs reserve the right to add witness to this list for good cause, consistent with this Court's March 15, 2019 Scheduling Order (ECF No. 688) at 1. Plaintiffs object to deposition designations from the underlying patent cases being played or read as trial testimony (as opposed to being introduced as exhibits) in this case and reserve rights to file a Motion *in Limine* precluding any such use.

Live

1. A corporate representative of Defendants
2. Any live witness identified on Defendants' live witness list
3. Custodian of Records for Defendants
4. Jim Benton
5. June Bray
6. Robert Carnevale
7. Mark Devlin
8. Kapil Gupta
9. William Kane
10. Peter Ludwig
11. Maureen Cavanaugh
12. Jinping McCormick
13. William Meury
14. Sean Moriarty
15. Bharati Nadkarni
16. Charles Ryan
17. Brenton Saunders
18. Julie Snyder
19. David Solomon
20. Marco Taglietti
21. Teva Custodian of Records
22. Dr. Ernst R. Berndt
23. James Bruno
24. Prof. Einer Elhauge
25. Dr. Nathan Hermann
26. George W. Johnston, Esq
27. Dr. Russel L. Lamb
28. Dr. Lon S. Schneider
29. Prof. Jay Thomas
30. Diana Wilk

Video

1. Eric Agovino
2. Katrina Curia
3. James Finchen

4. Jason Harper
5. Patrick Jochum
6. James Lah
7. Bob Lahman
8. Seth Silber
9. Gopalakrishnan Venkatesan

B. DEFENDANTS' WITNESS LIST

Forest hereby provides a list of witnesses whom Forest intends to call live at trial during Defendants' case-in-chief. This list does not include those witnesses who Defendants may call by video, but all deposition designations and objections are appended hereto as Exhibit 5. In addition to the witnesses listed below, Forest reserves the right to call in its case-in-chief witnesses listed on the Plaintiffs' witness list, and to revise this list based on decisions by the Court on the parties' Motions *in Limine*, decisions on other motions, the presentation of evidence in Plaintiffs' case-in-chief, or based on good cause, consistent with this Court's March 15, 2019 Scheduling Order (ECF No. 688) at 1.

The identification of a witness on this list is not an indication or representation that Forest either controls a witness or can compel his or her attendance at trial, and thus, Forest reserves all rights to play or read the deposition testimony of any witness on this list who does not appear live at trial.

1. Any witness identified on Plaintiffs' live witness list
2. Eric Agovino
3. Jim Benton
4. Alexandra Bonelli
5. June Bray
6. Joseph Brennan
7. Robert Carnevale
8. Napoleon Clark
9. Dr. Pierre-Yves Cremieux
10. Mark Devlin
11. Lawrence Doud
12. Dr. Martin R. Farlow
13. James Finchen
14. Dr. Lona Fowdur
15. Philip Green

16. Patrick Jochum
17. William Kane
18. Bruce Kohrman
19. Dr. Roberto Malinow
20. Christopher Masseth
21. Jinping McCormick or DRL Representative
22. Hon. Roderick McKelvie
23. Lei Meng
24. William Meury
25. Brad Pine
26. Jenna Plouffe
27. LuMarie Polivka-West
28. David L. Rosen
29. Barry Rovner
30. Dr. Charles Ryan
31. Brenton Saunders
32. Seth Silber
33. Julie Snyder
34. David Solomon
35. Marco Taglietti

X. RELIEF SOUGHT

Plaintiffs, on behalf of themselves and the Class (as defined by Order of the Court), seek the following relief pursuant to 15 U.S.C. § 15(a) (Clayton Act, § 4):

1. Awarding Plaintiffs and the Class threefold the damages sustained, by the Class in an amount which may be proven at trial, together with interest thereon;

2. The costs of suit, including a reasonable attorney's fee; and

3. Such other relief as this Court deems appropriate.

Date: 5/1/2019

Chief United States District Judge

Date: April 30, 2019

/s/ Dan Litvin

Date: April 30, 2019

/s/ Martin M. Toto

Bruce E. Gerstein
Joseph Opper
Dan Litvin
Kimberly M. Hennings
Garwin Gerstein & Fisher LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com
jopper@garwingerstein.com
dlitvin@garwingerstein.com
khennings@garwingerstein.com

David C. Raphael, Jr.
Erin R. Leger
Smith Segura & Raphael, LLP
3600 Jackson Street, Suite 111
Alexandria, LA 71303
Tel: (318) 445-4480
Fax: (318) 487-1741
draphael@ssrllp.com

Stuart E. Des Roches
Andrew W. Kelly
Odom & Des Roches, LLC
650 Poydras Street, Suite 2020
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078
stuart@odrlaw.com

Russ Chorush
Miranda Jones
Heim Payne & Chorush, LLP
1111 Bagby, Suite 2100
Houston, TX 77002
Tel: (713) 221-2000
Fax: (713) 221-2021
rchorush@hpcllp.com

Counsel for JM Smith Corporation d/b/a Smith Drug Company and the Direct Purchaser Class

David F. Sorensen
Ellen T. Noteware

Heather K. McDevitt
Martin M. Toto
John H. Chung
William H. Bave, III
Michael E. Hamburger
Kristen O'Shaughnessy
White & Case LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200

Christopher M. Curran
J. Mark Gidley
White & Case LLP
701 Thirteenth Street, NW
Washington, DC 20005
Telephone: (202) 626-3600

Heather M. Burke
White & Case LLP
3000 El Camino Real
5 Palo Alto Square, 9th Floor
Palo Alto, CA 94306
Telephone: (650) 213-0300
Kevin C. Adam
White & Case LLP
75 State Street, Floor 24
Boston, MA 02109
Telephone: (617) 979-9300

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.

Berger Montague PC
1818 Market Street
Suite 3600
Philadelphia, PA 19103
(215) 875-3000
(215) 875-4604 (fax)
dsorensen@bm.net
enoteware@bm.net

Peter Kohn
Joseph T. Lukens
Faruqi & Faruqi, LLP
1617 JFK Boulevard
Philadelphia, PA 19103
(215) 277-5770
(215) 277-5771 (fax)
pkohn@faruqilaw.com
jlukens@faruqilaw.com

Counsel for Rochester Drug Co-Operative, Inc. and the Direct Purchaser Class